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### Accessible Version

July 29, 2020

The Honorable Lamar Alexander  
Chairman  
The Honorable Patty Murray  
Ranking Member  
Committee on Health Education Labor and Pensions  
United States Senate

The Honorable Frank Pallone Jr.  
Chairman  
The Honorable Greg Walden  
Republican Leader  
Committee on Energy & Commerce  
House of Representatives

### Public Health Preparedness: HHS Has Taken Some Steps to Implement New Authority to Speed Medical Countermeasure Innovation

The Coronavirus Disease 2019 (COVID-19) pandemic as well as past infectious disease outbreaks such as the 2015 Middle East Respiratory Syndrome outbreak raise concerns about our nation’s vulnerability and capacity to prevent or mitigate potential health effects from exposure to such threats. Medical countermeasures are drugs, vaccines, and devices to diagnose, treat, prevent, or mitigate potential health effects of exposure to chemical, biological, radiological, and nuclear (CBRN) agents and emerging infectious diseases, such as influenza pandemics.<sup>1</sup> Our prior work has noted that responding to the ever-changing nature and broad array of CBRN threats often entails developing new technologies and approaches, while the process of researching and developing medical countermeasures is lengthy, complex, and expensive.<sup>2</sup> Further, several challenges, including low profitability, intellectual property rights, and the general lack of a commercial market for some medical countermeasures may reduce incentives for pharmaceutical and medical device manufacturers to invest time and money to develop these products instead of others that may be more profitable.<sup>3</sup>

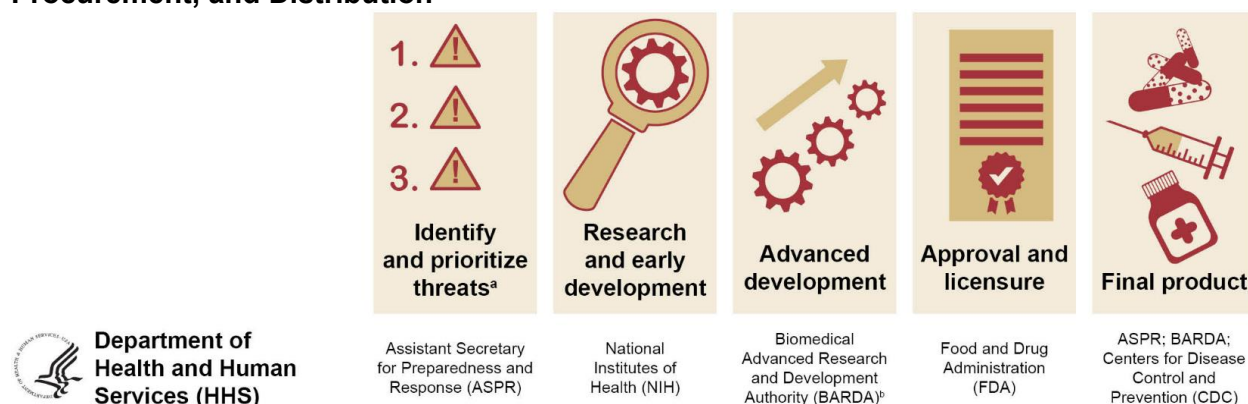
<sup>1</sup>We use the term medical countermeasures to also include technologies that might assist the development or use of medical countermeasures. CBRN agents can be natural, accidental, or intentional in origin.

<sup>2</sup>GAO, *National Biodefense Strategy: Additional Efforts Would Enhance Likelihood of Effective Implementation*, [GAO-20-273](#) (Washington, D.C.: Feb. 19, 2020); and GAO, *Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization*, [GAO-14-442](#) (Washington, D.C.: May 15, 2014).

<sup>3</sup>See GAO, *National Preparedness: HHS Is Monitoring the Progress of Its Medical Countermeasure Efforts but Has Not Provided Previously Recommended Spending Estimates*, [GAO-14-90](#) (Washington, D.C.: Dec. 27, 2013); and GAO, *Biological Defense: Additional Information That Congress May Find Useful as It Considers DOD’s Advanced Development and Manufacturing Capability*, [GAO-17-701](#) (Washington, D.C.: July 17, 2017).

Several federal departments and agencies have responsibilities for assessing, developing, and procuring medical countermeasures to address CBRN priority threats. The Department of Health and Human Services (HHS) leads the federal government in identifying needed medical countermeasures and for engaging with industry to develop and procure them (see fig. 1). Within HHS, the Office of the Assistant Secretary for Preparedness and Response (ASPR) leads federal medical and public health preparedness and response coordination, which includes providing support for developing, procuring, and planning for the effective use of medical countermeasures. ASPR is also responsible for managing the Strategic National Stockpile.<sup>4</sup> In addition to HHS agencies, the Department of Homeland Security and Department of Defense (DOD) also have responsibilities for addressing CBRN threats.<sup>5</sup>

**Figure 1: HHS’s Responsibilities for Medical Countermeasure Assessment, Development, Procurement, and Distribution**



Source: GAO analysis of HHS information. | GAO-20-601R

<sup>a</sup>ASPR leads the Public Health Emergency Medical Countermeasures Enterprise, a federal interagency body that is responsible for providing recommendations on medical countermeasure priorities and development and procurement activities.

<sup>b</sup>BARDA, an agency within ASPR, supports the advanced development and procurement of drugs, vaccines, and other medical countermeasure products. In some cases, BARDA also funds earlier stage research and development for medical countermeasures. It carries out this mission through public-private partnerships with industry and others.

In 2016, Congress passed and the President signed into law the 21st Century Cures Act to, among other things, help accelerate medical product development and innovations, including support for development of medical countermeasures.<sup>6</sup> Specifically, the Act authorized ASPR’s Biomedical Advanced Research and Development Authority (BARDA) to establish a public-private partnership to foster and accelerate the development of medical countermeasures.<sup>7</sup> Under this authority, BARDA may enter into an agreement with an independent, nonprofit entity to foster and accelerate the development and innovation of medical countermeasures and

<sup>4</sup>The Strategic National Stockpile contains pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out.

<sup>5</sup>The Department of Homeland Security also supports federal efforts to prepare for and respond to CBRN threats by assessing threat risks and coordinating response efforts. In addition, the DOD has responsibility for research, development, and acquisition of medical countermeasures for armed forces personnel.

<sup>6</sup>Pub. L. No. 114-255, 130 Stat. 1033 (2016).

<sup>7</sup>Pub. L. No. 114-255, § 3084, 130 Stat. at 1141 (codified, as amended, at 42 U.S.C. § 247d-7e(c)(4)(E)). BARDA supports the advanced development and procurement of needed medical countermeasures by providing technical assistance, grants, other funding, and engagement with industry through public-private partnerships. This includes technical assistance for regulatory approval and support for manufacturing toward the goal of inclusion of new medical countermeasures in the Strategic National Stockpile.

technologies, including through the use of venture capital practices and methods.<sup>8</sup> To implement this authority, BARDA will need to identify, select, and enter into a public-private partnership with such an entity, known as a medical countermeasures innovation partner (innovation partner) under the 21st Century Cures Act.<sup>9</sup> BARDA had not entered into a partnership with a nonprofit entity as of June 2020.

BARDA enters into other public-private partnerships to accomplish its mission, such as by providing funding to support a university's or company's efforts to develop countermeasures, (e.g. vaccines and therapeutics that bolster pandemic preparedness and response) and helping to accelerate development, while also sharing cost and risk with the private entity. However, according to HHS officials, the agency has not previously partnered with an entity that can use venture capital practices and methods—that is, make investments in companies developing promising, innovative products.<sup>10</sup> The Central Intelligence Agency (CIA) and DOD's Department of the Army (Army) have each partnered with nonfederal, nonprofit entities that use venture capital practices and methods to invest federal funds to meet strategic government needs, but such partnerships are uncommon in the federal government.<sup>11</sup>

The 21st Century Cures Act includes a provision for us to review activities conducted under the medical countermeasures innovation partner authority.<sup>12</sup> This report describes the status of BARDA's implementation of the innovation partner authority.

To describe the status of BARDA's implementation of the innovation partner authority, we reviewed relevant statutes and BARDA documentation regarding its plans for implementation, and actions taken to implement, this authority. We reviewed information BARDA collected in its two requests for information (RFI) from venture capital industry and other stakeholders. We reviewed the responses to identify stakeholder reported comments and whether respondents stated they could meet the innovation partner eligibility requirements set forth in the 21st Century Cures Act.<sup>13</sup> We interviewed officials from BARDA to learn about the agency's efforts to implement the authority, key information the agency obtained from interviews with its

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<sup>8</sup>The authority expires on September 30, 2023.

<sup>9</sup>BARDA refers to the medical countermeasures innovation partner as the Managing Entity. We use the term innovation partner in this report to refer to this entity.

<sup>10</sup>BARDA officials defined venture capital as private, equity-based financing. BARDA officials told us they anticipate that the innovation partner will employ all methods commonly used in venture capital to carry out its objectives.

<sup>11</sup>We identified two partnerships between federal agencies and nonfederal nonprofit entities using venture capital practices that were similar to the partnership authorized by the 21st Century Cures Act and active at the time of our review. First, the CIA partnered with In-Q-Tel, a nonprofit company, in 1999 to invest in intelligence and other innovation. Since it was established, In-Q-Tel has used venture capital practices to invest federal funds for several federal partners. Second, the Army partnered with nonprofit OnPoint Technologies in 2003 to establish its Army Venture Capital Initiative to invest in priorities for the Army. In addition to these two active partnerships, the National Aeronautics and Space Administration partnered with a nonprofit venture capital company, Red Planet Capital, in 2006, but the partnership was terminated in 2007. See Congressional Research Service, *Agency-Related Nonprofit Research Foundations and Corporations, R46901* (December 9, 2019), and Timothy Webb et al., *Venture Capital and Strategic Investment for Developing Government Mission Capabilities*, (Santa Monica, CA: RAND Corporation, 2014).

<sup>12</sup>Pub. L. No. 114-255, § 3084, 130 Stat. at 1143.

<sup>13</sup>In addition to being an independent nonprofit entity not within HHS, the 21st Century Cures Act outlined other eligibility requirements, including that the innovation partner has experience creating linkages between innovators and investors and experience related to technical and regulatory considerations for medical countermeasure development.

stakeholders, and the remaining steps and time frame for entering into an agreement with an innovation partner. We also reviewed documentation about two other federal partnerships with nonprofit nonfederal entities that have used venture capital practices to make strategic investments and that were in operation at the time of our review. Finally, we interviewed relevant officials from the Army to understand their experiences establishing their venture capital partnership.<sup>14</sup>

We conducted this performance audit from November 2019 to July 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our finding and conclusion based on our audit objective.

### **Status of BARDA's Implementation of the Medical Countermeasures Innovation Partner Authority**

BARDA has taken steps to implement the medical countermeasures innovation partner authority, but as of June 2020, the agency had not selected the innovation partner that would use federal funding and venture capital practices and methods to invest in companies developing medical countermeasures. In an effort to implement the authority, BARDA has developed a vision for the innovation partner, staffed a division to manage the authority, determined an initial amount of funding for the partnership, solicited and considered feedback from knowledgeable stakeholders, and developed preliminary plans for structuring the partnership. Officials explained this partnership approach requires due diligence to fully develop because it is new to the agency. BARDA officials noted that they had intended to release a request for proposals to solicit a potential innovation partner by the end of February 2020 and select a partner by the end of September 2020. However, they told us that, mainly due to the agency's responsibilities for developing and procuring medical countermeasures in response to the COVID-19 pandemic, these steps have been delayed.<sup>15</sup>

#### **Vision for the innovation partner.**

BARDA officials said they envisioned the innovation partner would invest in potentially transformative medical countermeasures and technologies with broad use, operating quickly and flexibly to make promising investments—including investments in companies that might not typically partner with government. The goal of these investments is to affect the rapid development of tools and technologies to improve the nation's preparedness posture against known and unknown threats, such as COVID-19. For example, according to agency officials, the innovation partner could, on BARDA's behalf, seek out and invest in companies that are developing energy sources to power personal wearable technologies that detect if an individual has an infection resulting from a biological threat, such as a viral infection. BARDA officials also discussed other examples of countermeasures the innovation partner might invest in, such as improvements to drug administration methods from intravenous to oral administration, reducing the needed amount of trained staff and supplies.

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<sup>14</sup>We did not interview CIA officials during the course of this review.

<sup>15</sup>BARDA officials told us they have focused their efforts on COVID-19 response activities since February 2020, including through funding announcements to support diagnostics and other countermeasures. Officials told us that based on their COVID-19 work to date, they thought the innovation partner, once awarded, could help to advance new medical countermeasures for COVID-19 or future pandemics.

According to BARDA officials, BARDA will not prescribe the products in which it wants the innovation partner to invest; rather, the agency will regularly provide the partner with a description of strategic priorities and allow the innovation partner the autonomy to make investments relative to those priorities. This is in contrast to some of BARDA's other public-private partnerships that are used to develop specific medical countermeasures, such as providing funds to develop diagnostic tests or vaccines for COVID-19 or combat antibiotic-resistant bacteria.<sup>16</sup>

According to BARDA officials, the compensation model for the innovation partner must be consistent with Internal Revenue Service rules regarding reasonable compensation for nonprofit corporations and will be finalized once an award is made. However, officials noted that models include reimbursing the innovation partner for administrative costs, or establishing a pre-determined reimbursement rate.<sup>17</sup> Officials stated that they intend to maximize this public-private partnership's benefit to the government by putting as much funding as possible towards investments and minimizing administrative costs.

BARDA expected the innovation partner to make its best effort to maximize the amount of the government's total initial investments, according to agency documents describing plans for the innovation partner. The agency plans for the innovation partner to do this by attracting private investors that share BARDA's vision and goals to match government funds on a one-to-one ratio. For example, officials said if BARDA provides the innovation partner with \$10 million to invest, the innovation partner will be encouraged to find other partners who will collectively invest \$10 million or more in matching funds. According to officials, this larger pool of funds would allow the innovation partner to share both the costs and risks associated with investments with the private sector while improving the chances that products will have commercial and strategic success.

### **Staffing and funding actions.**

BARDA staffed a division to manage the innovation partnership and determined an initial amount of funding for the partnership. Specifically, newly added staff in BARDA's Division of Research, Innovation, and Ventures (DRIVE) will manage the innovation partner's investments.<sup>18</sup> (See text box.) According to officials, BARDA hired knowledgeable staff, including contractors, who have experience with venture capital practices to help the agency assess the qualifications and capabilities of entities interested in competing to be the innovation partner. BARDA officials told us that these new staff have both the expertise to assist in evaluating strategic investment decisions based on the market research and analyses

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<sup>16</sup>For example, as of May 2020, BARDA had made 33 awards to develop a variety of products and manufacturing mechanisms to address COVID-19, such as diagnostic tests, vaccines, therapeutics, and manufacturing capabilities through two funding announcements. The funding announcements indicated that academic institutions, non-profit organizations, non-governmental organizations, government laboratories, and private sector organizations were eligible for the awards. In addition, BARDA awarded grants to multiple entities through the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program for the development of antibiotics, diagnostics, vaccines and other products to combat drug-resistant bacteria. CARB-X requires grantees to share in the costs of research and development by contributing at least 30 percent of the cost of the project.

<sup>17</sup>Venture capital entities, like the innovation partner, can be compensated in different ways. Providing a set annual base salary for work performed in addition to a percentage of future proceeds from successful investments—i.e., investments later sold—is one option, according to BARDA officials.

<sup>18</sup>BARDA established DRIVE in 2018.

conducted by the innovation partner and the ability to ensure that BARDA's interests are protected.



#### Division of Research, Innovation, and Ventures (DRIVE)

According to the Biomedical Advanced Research and Development Authority (BARDA), DRIVE will leverage public-private partnerships to bring together ideas from the medical, scientific, and venture capital communities. DRIVE is made up of four components using different mechanisms to invest in medical countermeasure development:

- **DRIVE Ventures**—will manage BARDA's medical countermeasures innovation partner authority, whereby BARDA will partner with a nonprofit to invest in promising products using venture capital practices.
- **DRIVE-X**—will provide funding to companies, universities, or others for medical countermeasure development in targeted areas.
- **DRIVE Accelerators**—will identify innovation for further investment and provide support services.
- **DRIVE Launch**—will address gaps that require nontraditional approaches to medical countermeasure development.

Source: BARDA | GAO-20-601R

BARDA plans to award the innovation partner a minimum of \$10 million per year.<sup>19</sup> The President's budget proposal for fiscal year 2021 has requested \$36 million for DRIVE.<sup>20</sup> According to BARDA officials, this includes up to \$20 million for the innovation partner to support investments.<sup>21</sup> With the federal investment and the matching funds the innovation partner will be encouraged to identify through other nonfederal sources, BARDA officials said they planned for the innovation partner to make some successful early investments that will garner additional support and funding from private investors. In the long-term, the ultimate goal will be to reinvest BARDA's revenues generated from investments rather than using additional appropriations.

#### Stakeholder feedback.

To engage potentially interested partners and solicit feedback on development of the innovation partnership from venture capital entities and other stakeholders, BARDA issued two RFIs and

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<sup>19</sup>The 21st Century Cures Act, which authorized BARDA to enter into an agreement with an innovation partner, did not provide an appropriation for the innovation partnership.

<sup>20</sup>Department of Health and Human Services, *Fiscal Year 2021 Public Health and Social Services Emergency Fund: Justification of Estimates for Appropriations Committee*. Each year, the President submits a fiscal year budget request to Congress providing detailed estimates of the financial operations of federal agencies and programs.

<sup>21</sup>Depending on the maturity of the projects selected for investment, BARDA officials told us that they anticipated that the innovation partner could make three or four investments with \$10 million in government funding each year.

met with over 60 stakeholders, organizations, accelerators, and interested parties.<sup>22</sup> For example, BARDA officials told us they met with officials familiar with the Army Venture Capital Initiative and the CIA's venture capital partnership with In-Q-Tel, as well as federal officials familiar with other federal public-private partnerships.<sup>23</sup> Through this engagement with stakeholders, federal officials, and others, BARDA officials identified suggestions for how to develop their own partnership and best practices. According to documents from BARDA regarding their plans to implement the authority, officials used the RFI responses and their meetings with stakeholders to understand venture capital options to fulfill the innovation partner authority.

According to our review of the RFI responses, stakeholders made suggestions for and comments about aspects of the innovation partnership, including the structure of the partnership, the eligibility requirements for the innovation partner, and general venture capital practices related to funding and investment.<sup>24</sup> Stakeholders also identified a number of concerns regarding aspects of the agency's plans for the innovation partner, which stakeholders indicated could hinder BARDA's implementation of the authority and ability to find an innovation partner. BARDA officials told us they were assessing options for mitigating the three main concerns they identified:

- There is a statutory limit on the amount of annual salary, including for those paid through a grant or other extramural mechanism, that can be paid to an individual from HHS's annual appropriation, not to exceed that of an Executive Level II salary.<sup>25</sup> Several stakeholder comments indicated that this limit is too low to attract an individual or entity to manage the innovation partner venture capital fund. BARDA officials were interested in how stakeholders would address this challenge. In their second RFI, BARDA requested that respondents provide financial models and projections, including how salaries and other fees would be paid. BARDA officials noted they were confident there were highly qualified entities interested in the innovation partnership despite the salary restriction.
- The 21st Century Cures Act requires, among other things, that the innovation partner be a nonprofit entity, which some stakeholders reported could exclude some entities from the partnership.<sup>26</sup> Further, BARDA officials told us the innovation partner, as a nonprofit entity, would be required to reinvest BARDA's share of any returns it makes into future

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<sup>22</sup>BARDA received more than a dozen responses to the first RFI—issued in January 2019—wherein respondents indicated an interest in becoming the innovation partner, demonstrated their eligibility and qualifications for the innovation partner by outlining how they meet the eligibility requirements set forth in the 21st Century Cures Act, and provided examples of previous investment and partnership successes. BARDA received more than two dozen responses to the second notice—issued in October 2019—wherein respondents provided questions, comments, suggestions, and concerns related to BARDA's draft solicitation and requirements for the innovation partner.

<sup>23</sup>The Army is in partnership with OnPoint Technologies to manage its Army Venture Capital Initiative to invest in priorities for the Army. The CIA is in partnership with In-Q-Tel to invest in intelligence and other innovation.

<sup>24</sup>In total, BARDA received over 150 questions, comments, suggestions, and concerns from stakeholders to their RFI notices regarding the innovation partnership.

<sup>25</sup>The salary cap for fiscal year 2020 was \$197,300. Such a salary cap is typically included in HHS annual appropriations. See, e.g., Pub. L. No. 116-94, div. A, tit. II, § 202, 133 Stat. 2534, 2577 (2019); Pub. L. No. 115-245, div. B, tit. II, § 202, 132 Stat. 2981, 3089 (2018); Pub. L. No. 115-141, div. H, tit. II, § 202, 132 Stat. 348, 735 (2018). BARDA officials noted that the CIA does not have a similar salary cap for their venture capital partner; Army officials also told us they do not have a similar salary cap for their venture capital partner.

<sup>26</sup>BARDA officials told us they had also decided, based on their stakeholder research, that only entities with an established nonprofit entity will be eligible to become the innovation partner.

investments made through the partnership.<sup>27</sup> According to BARDA officials, some stakeholders noted that they would not be interested in partnering with BARDA because, as a venture capital firm, their goal is to maximize returns on investments. BARDA officials stated that while they understood that the nonprofit requirement might disqualify some interested entities, it is required by statute. They noted there are many entities that also invest returns in additional technologies that benefit the fund's stated mission, instead of paying proceeds to investors.

- Some stakeholders expressed concerns regarding the uncertainty of federal funding streams. BARDA officials also noted stakeholder concerns regarding being able to find other venture capital firms with which to partner because of the tie to the government. To the extent the innovation partner's funding depends on annual appropriations, uncertainty about the availability of federal funding in future years may present an obstacle to BARDA to invest in promising technologies. To address this concern, BARDA officials said they were considering a suggestion from some RFI respondents and stakeholders on a way to alleviate the risk associated with the uncertainty of future federal funding. Specifically, the innovation partner could set up a reserve fund each year using its award and distribute the funds from year to year for the life of the investments made using the specific reserve fund. This would allow the innovation partner to create a reserve for each year it receives federal funding that it could use to support the life of a funded project without reliance on consistent federal funding.<sup>28</sup> However, BARDA officials stated that such an approach will need to be determined with the innovation partner once an award is made.

### **Preliminary planned structure and oversight.**

BARDA officials have developed preliminary plans for structuring and overseeing the agreement with the innovation partner, which officials say will be finalized when the agency makes the award. According to documentation from BARDA regarding its plans to implement the innovation partner authority, the agency will use a type of agreement known as an "other transaction" agreement to structure the innovation partner agreement with the innovation partner entity. As we have previously reported, other transaction agreements are generally not subject to federal laws and regulations applicable to federal contracts or financial assistance.<sup>29</sup> As a result, officials from multiple agencies have told us this approach provided them flexibility to develop customized agreements with entities and accomplish projects that they could not

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<sup>27</sup>According to BARDA officials, traditional venture capital funds return proceeds of the fund to investors. In contrast, the innovation partner will not return proceeds to the government but will reinvest them in perpetuity. Officials said they expected the proceeds on the government investments would be reinvested into further investments.

<sup>28</sup>For the initial award, BARDA plans to use funds from its fiscal year 2020 advanced research and development appropriation, which the agency must obligate within two years, according to officials. The awardee's use of funds will be governed by the agreement with BARDA.

<sup>29</sup>While other transactions allow for a more flexible, customized agreement between agency and contractor, the agency is expected to ensure the other transaction agreement is designed to align with the government's overall mission and needs and with consideration of the best interests of the government. We and others have previously reported that agencies' use of other transactions has resulted in reduced accountability and transparency, in part, because such agreements may be exempt from the federal acquisition regulation and government cost accounting standards. GAO, *Federal Acquisitions: Use of Other Transaction Agreements Limited and Mostly for Research and Development Activities*, [GAO-16-209](#) (Washington, D.C.: Jan. 2016); GAO, *Intellectual Property: Information on the Federal Framework and DOD's Other Transaction Authority*, [GAO-01-980T](#) (Washington, D.C. July 17, 2001); and Congressional Research Service, *Department of Defense Use of Other Transaction Authority: Background, Analysis, and Issues for Congress*, R45521 (Washington, D.C.: February 22, 2019).



have been achieved using traditional contracting mechanisms.<sup>30</sup> According to BARDA officials, the innovation partner agreement would establish mechanisms to ensure oversight of the partner, such as a Joint Oversight Committee, which would make strategic decisions related to the partnership and include staff from both BARDA and the innovation partner. In our previous work, HHS officials told us that such a committee allowed the agency to play a more active role in a project than it would have had under a traditional contract.<sup>31</sup> BARDA officials also told us they envisioned establishing a charter agreement, which would provide BARDA and the government with additional protections and oversight.<sup>32</sup>

Further, BARDA officials explained that the agency plans to use what it learned from other federal agencies and their venture capital practices in structuring the innovation partnership. Specifically, officials stated that certain BARDA staff would have daily interaction with the innovation partner to provide regular input into and oversight of investments and other decision making. In contrast, Army officials we interviewed noted that the agency's oversight of its venture partner was too far removed, which Army officials said was problematic, because the Army was not involved enough to ensure that its partner was investing in technology that was beneficial to the government. According to an Army official, the Army is considering terminating its Army Venture Capital Initiative, in part, for this reason. As noted, BARDA plans to have regular interaction with the innovation partner, which could address some of these lessons.

### **Agency Comments**

We provided a draft of this report to HHS and DOD for comment. HHS did not provide comments on this report and DOD provided technical comments that we incorporated as appropriate.

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We are sending copies of this report to the appropriate congressional committees, and to the Secretaries of Health and Human Services and Defense. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-7114 or [deniganmacauleym@gao.gov](mailto:deniganmacauleym@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report include Shannon Legeer (Assistant Director), Rebecca Abela (Analyst in Charge), and Atiya Siddiqi. Also contributing were Laurie Pachter, Vikki Porter, Jennifer Whitworth, Yesook Merrill, and Robert Marek.

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<sup>30</sup>Agency officials that reported such flexibilities included officials from HHS and DOD. See [GAO-16-209](#) and [GAO-01-980T](#).

<sup>31</sup>See [GAO-16-209](#).

<sup>32</sup>BARDA officials explained the charter agreement is necessary because BARDA's agreement with the innovation partner will not extend to entities the innovation partner invests or partners with on investments—that is, BARDA will not enter into a contractual relationship with the other investment partners or invested companies—which is different from BARDA's prior other transaction agreements. Additionally, BARDA officials told that as a nonprofit entity, the innovation partner will be committed to the ensuring its investments were focused on BARDA's goals as outlined in its incorporating documents.

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